Australian Clinical Trials Alliance

YEAR 3 ACTIVITY WORK PLAN

Activity	**Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance**
Program	Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program
Organisation	Australian Clinical Trials Alliance Ltd
Activity Plan Timeframe	July 2019 to June 2020

CONTENTS

ACTIVITY PLAN SUMMARY

OVERVIEW

Department of Health Program Name: Medical Research Future Fund (MRFF) - Lifting Clinical Trials and Registries Capacity - Clinical Trials Networks Program

Activity Name: Strengthening the capacity, efficiency and effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance

Activity Start Date: 16 June 2017

Activity End Date: 30 September 2020

Objective:

ACTA is expanding and strengthening its strategic leadership and practical support for Clinical Trials Networks (CTNs), coordinating centres (CCs) and clinical quality registries (CQRs). This leadership includes:

- the development and implementation of a **national capacity-building framework** (the framework) to provide a comprehensive, evidence-based foundation and strategic roadmap to expand the capacity, capability, efficiency and effectiveness of CTNs in Australia; and
- building on **strategic partnerships** with stakeholders, including Government, working with members and Alliance partners to address clinical priorities for CTNs, and
- facilitating effective **sharing of experience, capacity and resources** between CTNs to accelerate the impact of research as a core part of a self-improving health system.

This Activity Plan outlines key activities to be undertaken in 2019–20. The Activity Plan has been developed in consultation with the Australian Clinical Trials Alliance (ACTA) Board, ACTA Reference Groups and Special Interest Groups and ACTA members, and draws on the sector's significant strengths and expertise. ACTA is committed to working closely with Government, our members and the broader health and research sector in Australia to help develop the CTNs as core components of a learning healthcare system.

This Activity Plan builds on ACTA's work to date under the program. In years 1 and 2 ACTA has focused on establishing Reference Groups and communities of practice; establishing programs of direct support to existing and emerging CTNs and training in clinical trials methodology; and conducting extensive groundwork through consultation with the sector, identifying barriers and good practices and development of guidance.

2019-20 is the last year of funding for ACTA under this program. ACTA's aim in the coming year will be to build on the work to date to deliver substantive and lasting impacts, with a sector that is stronger, more efficient and effective, and ready to meet the critical challenges awaiting us.

In the coming year ACTA will:

- Continue to provide and develop **ongoing services to the sector**, including support to new and emerging CTNs and training in clinical trial methods.
- Conduct a program of **dissemination and implementation activities** in support of the guidance developed in key areas.
- Develop and deliver **practical tools** to support the implementation of good practice.
- Complete an **evaluation** of the work conducting over the three years of funding under the MRFF, to understand the value generated and lessons to be learned for future activities.

ACTA will achieve these goals by:

- maintaining the **central coordination and program support** required to progress key priorities;
- continuing to **engage with the sector** to ensure that the work program informs and is informed by member priorities, expertise and needs; and
- maintaining an active program of **engagement with our broader community of stakeholders**, including policymakers, funders, health service providers and consumers.

KEY PRIORITIES AND PROGRAMS OF WORK

PROGRAMS OF WORK: YEAR 3

ACTA continues to work across eight key program areas, supported by ACTA program staff and overseen by multidisciplinary cross-sector Reference Groups drawn from the ACTA membership and a multitude of key stakeholders. Within program areas, time-limited projects will be undertaken, supported by standing Reference Groups or time-limited Working Groups, as required.

These **eight program areas** are:

A. **Efficient and Effective CTNs**
B. **CTN Sector Expansion**
C. **Impact and Implementation of CTN trials**
D. **Embedding Clinical Trials in Healthcare**
E. **Strengthening Consumer Engagement in Developing, Conducting and Reporting Clinical Trials**
F. **Research Prioritisation: Tools and Criteria**
G. **Innovative Trial Design**
H. **Innovative Outcome Data**

Priorities will be reviewed on an annual basis and informed by stakeholder views and consultation, including with Federal agencies. Program areas are mapped to the Funding Agreement priorities (see Appendix A). Note that some funds have not yet been allocated – these funds will be utilised to address emerging issues as they arise, with the approval of the Department of Health.

OVERARCHING PRINCIPLES

ACTA has developed a set of core principles that will underpin its approach to priority programs and activities. These principles will be refined through member consultation and activity will be reviewed regularly to ensure alignment.

Core principles include:

- **Collaborative and inclusive**: inviting all to participate.
- **Effective and efficient**: recognising that public monies support this activity.
- **Equitable**: addressing gaps and areas of need within Australia.
- **Flexible and responsive:** able to respond to the changing needs of patients, the sector and Governments as views mature.
- **Evidence-based:** using the best available information.
- **Patient-centred:** involving consumers in all stages of the research continuum.
- **Innovative:** looking for novel methods that minimise cost.
- **Robust**: effective governance within a clear operating framework.
- **Defensible:** providing evidence of the impact of funding on sector capacity

2019–2020 ACTIVITIES AND DELIVERABLES

PROGRAM PRIORITY ACTIVITY

GROUP A: EFFICIENT AND EFFECTIVE CTNS

Goal:

Enable CTNs to operate in an effective and efficient manner.

Objectives:

- Describe activities undertaken by current networks.
- Identify factors critical to the success and failure of networks.
- Identify unmet needs to enhance the effectiveness and efficiency of networks.
- Promote linkage between networks and the sharing of expertise and tools.

Governance:

Board Sponsors	Leadership	Project Officer
Ms Rebecca James	Ms Melanie Gentgall Ms Donna Goldsmith Ms Karen Goulding A/Prof Katie Groom Ms Donna Reidlinger	Dr Megan Sanders

Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4
- Leadership and collaboration: 2,3

Year 3 Activity Deliverables. Program area A - Efficient and Effective CTNs:

Ongoing activities from Year 2		Deliverables	By when
A.6	**Identification of unmet needs, barriers and enablers** to the enhancement of the effectiveness and efficiency of CTNs. Following the development of a collection of guidance tools on good practice options for CTN operation, management and governance to address these needs, scope the optimal online repository to enable ready access for CTNs and collate the tools on ACTA's website.	1) Online resource of best practice options for CTNs.	Dec 2019
Year 3 Activities		**Deliverables**	**By when**
A.8	**Evaluation of CTN operational efficiency.** Develop an assessment tool drawing on critical success factors identified in year 2.	2) CTN Operational Assessment Tool. 3) A review identifying the prevalence of success factors across ACTA Member CTNs.	Sep 2019 Mar 2020

	Engage an external consultant to review ACTA member CTNs concerning critical success factors to identify successful CTNs with practices to share and CTNs with unmet needs.		
A.9	Development of **good practice tools and resources** for CTNs Continue the development of at least six good practice tools and resources for CTNs identified as high priorities by the sector. Disseminate and share these through a community of practice.	4) Six additional good practice tools and resources for CTNs.	2 in Sep 2019 2 in Jan 2020 2 in Apr 2020

GROUP B: CTN SECTOR EXPANSION

Goal:

The establishment of efficient, effective, and sustainable CTNs in areas of major importance to public health and the healthcare system.

Objectives:

- Identify and prioritise areas of need for the establishment of new CTNs.
- Develop and disseminate guidance framework for the formation of effective, efficient, and sustainable new networks.
- Assist and facilitate the formation of new networks, focusing on areas of need.

Governance:

Board Sponsors	Leadership	Project Officer
Prof Steve Webb Prof Chris Reid	Prof Alex Brown Prof Craig French Dr Jacqui Waterkeyn	Dr Megan Sanders

Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,3,5
- Leadership and collaboration: 1,4

Year 3 Activity Deliverables. Program area B - CTN sector expansion:

Ongoing activities from Year 2		Deliverables	By when
B.8	**Support for new CTNs.** Continue the successful program of strategic and logistical support for emerging and establishing CTNs through sharing resources, support and mentoring relationships.	1) Support provided to at least two emerging or establishing CTNs.	Jan 2020
B.9	Targeted **establishment of new CTNs** identified as priorities through the Sector-wide Gap Analysis conducted in Year 2. Identify key leaders and **facilitate discussions around establishing CTNs**, providing strategic and logistical support.	2) Facilitated discussions on CTN establishment with two identified priority disease or discipline areas.	Jan 2020
Year 3 Activities		**Deliverables**	**By when**
B.10	Development of **tools and resources to facilitate CTN establishment**. Develop guidance on the selection of an appropriate business structure to meet the needs of new CTNs. Review and optimise the guidance developed in Year 2.	3) New CTN business structure guidance tool. 4) Guidance for New CTNs v2.0.	Sep 2019 Jun 2020

GROUP C: IMPACT AND IMPLEMENTATION OF CTN TRIALS

Goal:

Maximise, and measure the value of clinical trials to the community and the healthcare system, including the consideration of the implementation of trial results into standard care

Objectives:

1. Establish a community of practice involving both clinical trial networks, experts in implementation science, and end-users to grow capacity in networks to facilitate effective implementation of the results of trials conducted by networks.
2. Disseminate and promote methods to clinical trial networks:
    - To facilitate the design of trials that optimises capacity for implementation;
    - To facilitate the appropriate implementation of trial results;
    - To allow measurement of change in practice, coordinated with the conduct of trials;
    - To measure the impact on practice, including economic impact following the implementation of trial results (i.e. return-on-investment studies).

Governance:

Board Sponsors	Leadership	Project Officer
Prof Judith Trotman Prof Steve Webb	Prof Alan Cass Prof Sally Green Prof Chris Levi	TBD

Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 3,4,6
- Leadership and collaboration: 1,2,3,4

Year 3 Activity Deliverables. Program area C - Impact and Implementation of CTN Trials

Year 3 Activities		Deliverables	By when
C.9	Build a **community of practice** that engages CTNs, AHRTCs, experts in implementation science, and leaders in the healthcare sector with the shared goal of optimisation of implementation of evidence generated by trials. Disseminate and implement the guidance documents developed in Year 2 for trialists, including at least one training opportunity.	1) At least one training opportunity on the implementation guidance documents.	Mar 2020
C.10	Develop and disseminate tools to measure the impact (or potential impact) of CTN trials.	2) At least one practical tool to estimate the impact of CTN trials.	Jun 2020
C.11	Collaborate with research funding bodies to identify mechanisms to evaluate the capacity for implementation and impact.	3) Report on key issues in the measurement of impact in trial funding proposals.	Jun 2020

GROUP D: EMBEDDING CLINICAL TRIALS IN HEALTHCARE

Goal:

Reduce the cost and shorten the duration of clinical trials by integrating clinical trial processes as a routine and integrated component of the healthcare system

Objectives:

- Define *embedding* of clinical trials within routine healthcare delivery.
- Describe and report examples of successful embedding.
- Develop a comprehensive model of embedding.
- Identify enablers and barriers to successful embedding.
- Create a community of practice among trialists who utilise embedding.
- Develop and implement a strategy to remove barriers and promote enablers, including elements related to the design and conduct of trials, the healthcare system, and public policy.
- Develop metrics that evaluate embedding.

Governance:

Board Sponsors	Leadership	Project Officer
Prof Vlado Perkovic Prof John Simes	A/Prof Tom Briffa Dr Ian Harris Ms Sue Jenkins-Marsh Prof Anthony Keech Dr Chris Williams Prof Nik Zeps	Ms Madeleine Enright & Ms Nicola Straiton

Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4,6
- Leadership and collaboration: 2,3

Year 3 Activity Deliverables. Program area D - Embedding Clinical Trials in Healthcare

Year 3 Activities		Deliverables	By when
D.9	**Comparative effectiveness clinical trial model** Evaluate national policies (such as NHMRC National Statement and Privacy Act) to define a pathway for comparative effectiveness trials to be deemed low- or negligible-risk, and a step-by-step guide to determine if a trial meets these criteria. Define comparative effectiveness research and standard of evidence required to demonstrate this status and associated guidance document for researchers.	1) A report and step-by-step guide on the assessment of low- or negligible-risk comparative effectiveness. 2) Guidance document defining the standard of evidence required for comparative effectiveness trials.	Feb 2020
D.10	**A community of practice** for researchers and health services that aim to achieve embedding. Develop a practical guide to assist researchers and institutions to better embed clinical trial activities as part of routine practice.	3) A practical guide for health service providers and clinical trialists on the embedding of trials.	Dec 2019

	Deliver at least one event on embedded trial design to provide expert panel feedback to optimise the design and identify potential barriers.	4) Workshop (or similar event) on embedded trial design.	Dec 2019
D.11	**Consumer information** for participation in low/negligible risk comparative effectiveness trials. Develop simplified, consumer-endorsed, standard content for patient information sheets and consent forms, with accompanying guidance, for participants in low/negligible risk comparative effectiveness trials.	5) Guidance and template for consumer-endorsed patient information sheets and consent forms.	May 2020

GROUP E: STRENGTHENING CONSUMER ENGAGEMENT IN DEVELOPING, CONDUCTING AND REPORTING CLINICAL TRIALS

Goal:

Strengthen the CTN sectors' capacity and ability to involve consumers in all activities across the research continuum.

Objectives:

- Identify and disseminate best practice options for the involvement of consumers in CTN activities.
- Develop and disseminate messages to the general community about the value of clinical trials, particularly around comparative effectiveness trials.

Governance:

Board Sponsors	**Leadership**:	**Project Officer**
Ms Rebecca James Mr Kieran Schneemann Prof John Zalcberg	Mr Alex Economides Ms Anne McKenzie A/Prof Angela Todd	Ms Nicola Straiton

Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4
- Leadership and collaboration: 1,2

Year 3 Activity Deliverables. Program area E - Strengthening Consumer Engagement in Developing, Conducting and Reporting Clinical Trials:

Ongoing activities from Year 2		**Deliverables**	**By when**
E.6	**Engagement** with consumers and CTNs, and literature **review** of international practice to identify **best practice options** for the involvement of consumers in CTN activities and CTN trials. Further develop guidance for CTNs and launch online toolkit for consumer involvement and engagement.	1) Online toolkit for consumer involvement and engagement launch.	Dec 2019
E.7	Identify optimal needs around **community awareness** of the role and value of clinical trials conducted by CTNs. Map current **clinical trial awareness initiatives**. Conduct consultation workshop for the research sector, consumers and stakeholders to identify challenges and opportunities e.g. broad community awareness of clinical trials, engagement of CALD communities, etc. Develop recommendations to guide future action to engage the general community and enhance clinical trial awareness.	2) Workshop on identifying opportunities and challenges of clinical trial awareness and engagement in the broader community. 3) Recommendation report from the workshop outcomes.	Nov 2019

Year 3 Activities		Deliverables	By when
E.8	**Consumer involvement and engagement** toolkit implementation. Continue to maintain, review and develop the consumer involvement and engagement toolkit following the initial launch. Promote and facilitate the online toolkit across the sector.	4) Two events (or webinars) to promote consumer involvement and engagement in clinical trials.	Jun 2020

GROUP F: RESEARCH PRIORITISATION: TOOLS AND CRITERIA

Goal:

To ensure that trials conducted by networks identify research questions with the greatest possible impact on health outcomes.

Objectives:

- Development and dissemination of best practice guidelines for prioritisation of clinical trials conducted by CTNs.

Governance:

Board Sponsors	**Leadership**:	**Project Officer**
Prof John Simes Mr Kieran Schneemann Ms Margot MacGillivray	A/Prof Rachael Morton Dr Haitham Tuffaha	Mrs Anitha Balagurunathan

Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 3
- Leadership and collaboration: 1

Year 3 Activity Deliverables. Program area F - Research Prioritisation: Tools and Criteria:

Ongoing activities from Year 2		**Deliverables**	**By when**
F.2	**Validation** of the Prioritisation Framework	1) Consultation with research funders to evaluate the Prioritisation Framework from their perspective.	Dec 2019
F.4	Prioritisation Framework **Implementation Pilot** Complete the pilot of Prioritisation Framework with selected CTNs, and report on outcomes. Revise the Framework to incorporate learnings from all activities.	2) Report on the piloted clinical trial prioritisation framework. 3) Prioritisation Framework v2.0.	May 2020 Jun 2020
Year 3 Activities		**Deliverables**	**By when**
F.5	**Dissemination and implementation** of Prioritisation Framework Dissemination activities and support for the implementation of the Prioritisation Framework, including at least one training opportunity.	4) At least one training opportunity on the clinical trial Prioritisation Framework.	May 2020

GROUP G: INNOVATIVE TRIAL DESIGN

Goal:

CTNs transition from the use of conventional trial designs to use of innovative trial designs, where appropriate.

Objectives:

- Facilitate the availability, dissemination, uptake, and evaluation of innovative methods of trial design.
- Influence policy and promote the development of shared infrastructure that can support innovative trial design.

Governance:

Board Sponsors	Leadership	Project Officer
Prof Steve Webb Prof Vlado Perkovic	Prof Andrew Forbes A/Prof Stephane Heritier Prof Rachel Huxley A/Prof Mustafa Khasraw A/Prof Kate Lee Dr Ann Solterbeck	Ms Madeleine Enright (interim)

Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4,5
- Leadership and collaboration: 2,3

Year 3 Activity Deliverables. Program area G - Innovative trial design:

Year 3 Activities		Deliverables	By when
G.6	Maintain a **community of practice** with expertise in design and analysis of innovative designs, and development of template protocols. Deliver a program of training opportunities for statisticians, methodologists and trialists on innovative trial designs, including at least three face-to-face workshops. Deliver a program of webinars covering a range of topics of interest to the clinical trials sector. Develop and deliver training materials for members of Data Safety Monitoring Boards on innovative trial designs, enabling re-use of the training materials.	1) Workshops on innovative trial designs. 2) Webinars for the clinical trials sector. 3) Training materials on innovative trial designs for Data Safety Monitoring Boards.	Jun 2020 Jun 2020 Jun 2020
G.7	Templates for **innovative trial methodology.** Develop and deliver templates for protocols and statistical analysis plans on innovative trial designs, for adaptation to individual trials.	4) Innovative trial designs protocol and statistical analysis plan templates.	Jun 2020
G.8	In collaboration with ACTA STInG, facilitate access to **centres of statistical expertise**.	5) Develop an online facility to identify statistical experts.	Jun 2020

	Identify biostatistics workforce capacity and develop a mechanism for trialists to access statistical expertise in key areas.		

GROUP H: INNOVATIVE OUTCOME DATA

Goal:

Widespread uptake of the use of linked data, automated PROMs, and registry datasets by CTN trials.

Objectives:

- Facilitate the availability, dissemination, and uptake of innovative methods for the collection of trial outcome data.
- Influence policy and promote the development of shared infrastructure that can support innovative methods for collection of trial outcome data which is relevant to real-world populations.

Governance:

Board Sponsors	Leadership	Project Officer
Prof Vlado Perkovic Prof Chris Reid Prof Steve Webb Prof John Zalcberg	Prof Dorota Doherty Dr Felicity Flack A/Prof Steven Tong	Ms Madeleine Enright

Linkage to MRFF funding agreement priorities (Appendix A)

- Priority activities: 1,2,4
- Leadership and collaboration: 2,3

Year 3 Activity Deliverables. Program area H - Innovative Outcome Data:

Year 3 Activities		Deliverables	By when
H.5	**Registry randomised trials** barriers Workshop of key stakeholders to respond to and address the barriers to uptake of registry randomised trials identified in the *RRT Enablers and Barriers report*.	1) Workshop on registry randomised trial barriers.	Jun 2020

ACTA CENTRAL: LEADERSHIP AND COLLABORATION

Goal:

To expand and strengthen ACTA's capacity to provide collaborative and strategic leadership and practical support for CTNs, CCs and CQRs.

Objectives:

- Ensure sustainable growth of ACTA capacity and expertise.
- Promote effective and cost-effective health care in Australia through investigator-initiated clinical trials.
- Provide a forum to facilitate communication and collaboration between clinical researchers, Governments, policymakers, healthcare providers, industry and consumers and identify areas for further development or activity.
- Measure ACTA's impact on the sector.

Governance:

Strategic	**Tactical**	**Operational**
ACTA Board	ACTA Advisory Council General Manager Senior Program Manager Communications Manager Reference Groups	Board sub-committees Finance and Operations Manager Project Officers Event and Communication Coordinators ACTA Secretariat

Year 3 Activity Deliverables:

Ongoing activities from Year 2		**Deliverables**	**By when**
Ap.22	**International Clinical Trials Day** Partner with key stakeholders to celebrate International Clinical Trials Day**.**	1) Annual Trial of the Year Awards.	
Ap.23	**Publications** Develop reference material for consumers and stakeholders to raise awareness about ACTA and evidence-based and value-based health care. Publish the work from the Reference Groups in peer-reviewed journals or alternative external publication instruments, where appropriate.	2) At least one online or physical publication on the value of investigator-initiated clinical trials.	Jun 2020
Ap.24, 25, 28	Provide a **forum for stakeholders** Hold two annual meetings of ACTA's Advisory Council. Facilitate at least two annual Special Interest Group meetings for SIGNet, ACTA STInG and the Registries. Hold an annual scientific meeting.	3) Two annual Advisory Council meetings. 4) At least two annual Special Interest Group meetings. 5) Annual scientific meeting.	Jun 2020 Jun 2020 Oct 2019
Ap.27	Complete a major redevelopment and upgrade of the **website and digital assets.**	6) Launch the new ACTA website.	Dec 2019

Year 3 Activities		Deliverables	By when
Ap.31	**Measure ACTA's impact** on the sector. Review the consolidated Program Evaluation Plan to measure the impact of ACTA's activity in expanding and enhancing the clinical trials and registries sector. Complete and report on the evaluation of all programs per the Program Evaluation Plan.	7) Program Evaluation Report.	Aug 2020
Ap.32	Delivery of **additional strategic projects** such as those prioritised by the Government, developed in collaboration with key stakeholders, or as stretch objectives for the Reference Groups. ACTA will prioritise responsiveness to the needs of government and other key collaborators. A pipeline of possible stretch objectives arising from the Reference Groups is being scoped, to be selected and prioritised in response to confirmation of available capacity and the completion of prior projects by each Reference Group. Possible work areas include shared services for CTNs, assessment of embedding practice for health service providers, increasing recruitment of trial participants, practical tools for prioritisation methodologies, ePROMS, and infrastructure around clinical trials data sharing.	8) Scope and deliver additional strategic projects, as selected in consultation with the Department of Health.	Jun 2020
Ap.33	**Annual Report**	9) Publish an annual report.	Dec 2019
Ap.34	Expand **Social Media** reach and engagement. Grow reach and impact across social media with paid components.	10) Report on social media activities and impact.	Jun 2020

APPENDIX A: MRFF FUNDING AGREEMENT PRIORITIES

The delivery of the Activity will include, but not be limited to, the following:

PRIORITY ACTIVITIES:

1. Identifying, agreeing and implementing best-practice guidelines to achieve optimal operational standards.
2. Facilitating knowledge sharing and professional development.
3. Identifying and addressing gaps and strategic opportunities in the CTN sector.
4. Developing and sharing tools and resources to enhance the quality, efficiency, and effectiveness of CTNs.
5. Cultivating thought leadership to drive contemporary models for research prioritisation and design.
6. Facilitating a robust approach to measuring the impact of ACTA's activity in expanding and enhancing the clinical trials and registries sector in accordance with the agreed Activity Work Plan.

LEADERSHIP AND COLLABORATION

1. Strengthening governance, advisory and working group structures.
2. Creating strategic collaborations and partnerships.
3. Fostering a culture of collaboration around areas of mutual interest and synergy.
4. Maintaining appropriate and widespread communication between ACTA members, and the broader health community through a range of publications, website and digital media, webinars and forums and communiques and policy briefs.